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| APPLICATION NO.         | FI      | LING DATE  | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------|---------|------------|----------------------|---------------------|------------------|
| 10/800,918 03/16/2004   |         | 03/16/2004 | Claude Singer        | 1662/495071         | 9628             |
| 23838                   | 7590    | 06/27/2005 |                      | EXAMINER            |                  |
| KENYON                  |         | ON         | HABTE, KAHSAY        |                     |                  |
| 1500 K STR<br>SUITE 700 | EEINW   |            | ART UNIT             | PAPER NUMBER        |                  |
| WASHINGT                | TON, DC | 20005      | 1624                 |                     |                  |

DATE MAILED: 06/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|   |  | Application No.                | Application No. Applicant(s)  |             |  |  |  |  |  |
|---|--|--------------------------------|---|-------------|--|--|--|--|--|
|   |  | 10/800,918                     | SINGER ET AL.   |             |  |  |  |  |  |
|   | Office Action Summary  | Examiner                       | Art Unit  |             |  |  |  |  |  |
|   |  | Kahsay Habte, Ph. D.           | 1624  |             |  |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  |  |                                |   |             |  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |  |                                |   |             |  |  |  |  |  |
| Status  |  |                                |   |             |  |  |  |  |  |
| 1)⊠   | Responsive to communication(s) filed on <u>11 May 2005</u> .   |                                |   |             |  |  |  |  |  |
| 2a)⊠  | This action is <b>FINAL</b> . 2b)□   |                                |   |             |  |  |  |  |  |
| 3)□   | Since this application is in condition for all   | owance except for formal mat   | ters, prosecution as to the   | e merits is |  |  |  |  |  |
|   | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  |                                |   |             |  |  |  |  |  |
| Disposition of Claims   |  |                                |   |             |  |  |  |  |  |
| 5)□<br>6)⊠<br>7)⊠   | Claim(s) <u>48-73</u> is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.  Claim(s) is/are allowed.  Claim(s) <u>48.50,59,60,64 and 73</u> is/are rejected.  Claim(s) <u>49,51-58,61-63 and 65-72</u> is/are objected to.  Claim(s) are subject to restriction and/or election requirement. |                                |   |             |  |  |  |  |  |
| Application Papers  |  |                                |   |             |  |  |  |  |  |
| 9) The specification is objected to by the Examiner.  |  |                                |   |             |  |  |  |  |  |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.   |  |                                |   |             |  |  |  |  |  |
|   | Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |                                |   |             |  |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  |  |                                |   |             |  |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  |  |                                |   |             |  |  |  |  |  |
| Priority under 35 U.S.C. § 119  |  |                                |   |             |  |  |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>   |  |                                |   |             |  |  |  |  |  |
| Attachment(s)   |  |                                |   |             |  |  |  |  |  |
| 2) Notic 3) Inform  | e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948 nation Disclosure Statement(s) (PTO-1449 or PTO/SI  | Paper Notice of 5) Notice of 1 | Summary (PTO-413)<br>s)/Mail Date<br>informal Patent Application (PTC | D-152)      |  |  |  |  |  |
| rape  | r No(s)/Mail Date <u>5/11/2005</u> .   | 6)                             |   |             |  |  |  |  |  |

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### **DETAILED ACTION**

1. Claims 48-73 are pending.

#### Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/11/2005 has been entered.

#### Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 5/11/2005 was filed before the mailing of the First Office Action after filing RCE on 1/11/2005. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 48, 50, 59-60, 64 and 73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention: In claims 48 and 51, the phrases, "about 90% or greater" or "about 95% or greater" are not clear. The term "greater" is ambiguous when it follows "about 90%" or "about 95%". For example for the phrase "about 90% or greater", it is unclear if the term "greater" applies to the 90% (i.e. greater than 90%, e.g. 91%) or if it applies for the phrase "about 90%" (i.e. greater than about 90%, e.g. 88%, 89%, 90%, 91%, etc.). The latter covers both greater and lower percentage numbers of the 90%. The same is true for the phrase "about 95% or greater". If the greater applies to the "95%", percentage numbers such as 96%, 97% are covered. In other hand, if the term "greater" applies to "about 95%", percentage numbers such as 94%, 95.2%, 96%, etc. are covered. See Ex parte Lee, 31 USPQ 2nd 1105, 1107; Amgen vs. Chugai, 13 USPQ 2nd 1737, 1787; 18 USPQ 2d 1016, 1030. Suggested is "about 90% or greater than 90%" for claim 48 and 60 and "about 95% or greater than 95%" for claims 50, 59, 64 and 73. Note that claim language in claims 49, 51, 58, 63, 65 and 72 are acceptable.

Note that no response to this rejection was submitted with the RCE filed on 5/11/2005.

## Objection

5. Claims 49, 51-58, 61-63 and 65-72 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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#### Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (571) 272-0667. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson (Acting SPE) can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kahsay Hable, Ph. D.

Examiner Art Unit 1624 Mark L. Berch Primary Examiner Art Unit 1624

KH June 23, 2005